REMARKS

I. Introduction

In response to the Office Action dated March 18, 2008, claims 2 and 10-35 have been cancelled, claim 1 has been amended, and new claims 36-41 have been added. Claims 1, 3-9 and 36-41 remain in the application. Re-examination and re-consideration of the application, as amended, is requested.

II. Claim Amendments

Applicant's attorney has made amendments to the claims as indicated above. These amendments focus the claims on certain embodiments of the invention that are designed to inhibit the formation of biofilms on medical devices.

The amendments to the claims are fully supported by the specification as filed and introduce no new matter. Specification support for a medical device made from a non-biodegradable and/or non-hydrolysable material as recited in claims 1 and 38 (e.g. a metallic or a biostable polymeric material respectively) can be found for example in paragraphs [0032], [0068] and [0103]. Specification support for medical devices coated with a composition that comprises a lectin disposed in a biodegradable polymer that can slough away from the medical device when the lectin is bound to the compound produced by a microorganism so as to inhibit formation of a biofilm on the surface of the medical device (as recited in claims 1 and 38) can be found for example in original claim 2, paragraph [0010] and Fig. 1C. Support for embodiments of the invention where the composition comprising the lectin is disposed on a region of the device having a mechanical structure that is compatible with the adherence of microorganisms (as recited in claim 41) can be found for example in paragraph [0104].

III. Prior Art Rejections

On page 6 of the Office Action, claims 1-5 and 7-9 were rejected under 35 US.C. §102(b) as being anticipated by U.S. Patent No. 6,625,479 to Weber et al. ("Weber"). On page 7 of the Office Action, claim 6 was rejected under 35 U.S.C. §103(a) as being unpatentable over Weber in combination with U.S. Patent No. 3,996,345 to Ullman et al. ("Ullman"). Applicant respectfully traverses these rejections for the reasons articulated below.

A. COMPARISON OF APPLICANT'S INVENTION WITH THE DEVICES DISCLOSED IN WEBER AND ULLMAN

INVENTION RECITED IN THE PENDING CLAIMS

Independent claims 1 and 38 are focused on an embodiment of the invention having a constellation of elements designed to inhibit the formation of a biofilm on a medical device. Specifically these claims recite a device constructed from a biologically stable material such as a metal or biostable polymeric material (i.e. one not readily altered in chemical makeup of physical state when implanted in vivo) that further includes a surface coated with a composition that: (1) comprises a lectin that can bind a compound produced by a microorganism capable of forming a biofilm on the surface of the medical device; and (2) comprises a biodegradable polymer that can slough away from the medical device when the lectin is bound to the compound produced by a microorganism so as to inhibit formation of a biofilm on the surface of the medical device. Embodiments of the invention that use this constellation of elements to inhibit formation of a biofilm on the surface of the medical device are described for example in paragraphs [0008]-[0010] of Applicant's specification.

U.S. PATENT NO. 6,625,479 TO WEBER ET AL.

U.S. Patent No. 6,625,479 to Weber et al. discloses an implantable sensor for use in the detection or quantitative measurement of an analyte in subcutaneous fluid, the sensor being biodegradable or hydrolysable in vivo (see, e.g. the abstract). Weber teaches that in operation, this biodegradable/hydrolysable sensor is placed in a subcutaneous location so that it degrades slowly over a period of time. Once the sensor has degraded to an extent that it has ceased to be functionally effective in the monitoring of analytes a fresh sensor can be simply injected or implanted and there is no need for the old sensor to be surgically removed. In this context, Weber teaches that, for reasons of safety, the sensor should degrade into material which is completely eliminated from the body. In practice, this requires that the sensor degrade into materials capable of passing through human kidney membrane to be excreted in urine or which can be metabolized by the body (see, e.g. column 3, lines 30-42). Weber further teaches that their

biodegradable/hydrolysable sensors can include analyte binding agents such as lectins (e.g. concanavalin A).

U.S. PATENT NO. 3,996,345 TO ULLMAN ET AL.

U.S. Patent No. 3,996,345 to Ullman et al. teaches optical means for determining analyte concentrations such as immunoassays employing antibodies and a fluorescer-quencher (F-Q) chromophoric pair, wherein one or both of the chromophoric pair are bonded to antibodies. Ullman teaches that microorganisms which can be assays using embodiments of their invention include Staphlococcus aureus and Escherichia coli.

B. APPLICANT'S RESPONSE TO THE REJECTIONS UNDER 35 U.S.C. §102(b)

On page 6 of the Office Action, claims 1-5 and 7-9 were rejected under 35 US.C. §102(b) as being anticipated by U.S. Patent No. 6,625,479 to Weber et al. ("Weber").

Applicants respectfully traverse the rejection. In particular, Weber cannot anticipate the invention recited in the claims as amended hereinabove because Weber fails to teach or suggest medical devices constructed to include both a metallic material **and** a biodegradable lectin composition (as recited in claim 1); and/or devices constructed to include both a surface comprising a biostable polymeric material **and** a biodegradable lectin composition (as recited in claim 38). Instead, Weber teaches devices made from completely biodegradable/hydrolysable materials designed to degrade and either pass through the human kidney membrane and then be excreted in urine or be metabolized by the body (see, e.g. column 3, lines 30-42). Because neither metals (e.g. titanium) nor biostable polymeric materials (e.g. Gortex or Teflon) are biodegradable/hydrolysable, Weber consequently fails to teach or suggest devices made from these materials, much less devices made from these materials that are further coated with a biodegradable lectin composition. For this reason, the Weber disclosure cannot anticipate the invention recited in the claims as amended hereinabove.

Applicants further traverse this rejection because the Weber disclosure also fails to teach the location limitation for this coating as found in step (c) of claims 1 and 38, namely one where the biodegradable lectin composition is disposed on the medical device at a location that allows it to slough away from the medical device when the lectin binds microbial compounds, so as to inhibit

formation of a biofilm on the surface of the medical device. In particular, a detailed analysis of Weber shows that this disclosure fails to mention any microorganisms and/or biofilms, much less devices designed to inhibit biofilm formation. For this additional reason, Weber cannot anticipate the invention recited in the claims as amended hereinabove.

As noted for example in M.P.E.P. 2131, a claim is anticipated only when a single prior art reference discloses each and every limitation in the claim. M.P.E.P. 2131 further states that in order to anticipate a claimed invention, a single art reference must show the identical invention in as complete detail as is contained in the claim and that "the elements must be arranged as required by the claim". Because the Weber disclosure fails to teach or suggest devices having the constellation of elements recited in Applicant's independent claims (e.g. ones including a metallic material and coated with a lectin that is disposed within a biodegradable polymer that can slough away from the surface of the medical device in order to inhibit the formation of biofilms), it cannot anticipate the claimed invention. For this reason, Applicants respectfully request a withdrawal of the rejection under 35 U.S.C. §102(b).

C. APPLICANT'S RESPONSE TO THE REJECTIONS UNDER 35 U.S.C. §103(a)

On page 7 of the Office Action, claim 6 was rejected under 35 U.S.C. §103(a) as being unpatentable over Weber in combination with U.S. Patent No. 3,996,345 to Ullman et al. ("Ullman").

Applicant respectfully traverses this rejection because, for example, the Ullman disclosure fails to remedy the above-noted deficiencies in the Weber disclosure. In particular, Ullman merely teaches assays of microorganisms. Ullman fails to teach or suggest devices constructed to include both a metallic material or a biostable polymeric material as well as a surface coated with a lectin composition. Moreover, Ullman further fails to teach or suggest devices having a lectin disposed within a biodegradable polymer that can slough away from the surface of the medical device in order to inhibit the formation of a biofilm on that device. Consequently, the disclosures in Weber and Ullman cannot be combined so as to produce the invention recited in the claims as amended hereinabove. For this reason, Applicants respectfully request a withdrawal of the rejection under 35 U.S.C. §103(a).

Applicant further notes that one of skill in the art would not be motivated to combine the disclosure of Ullman with the Weber disclosure because the devices disclosed in Ullman cannot degrade into materials capable of passing through human kidney membrane to be excreted in urine or which can be metabolized by the body (i.e. as taught by Weber at column 3, lines 30-42). Instead Ullman teaches conventional devices made from conventional materials that do not degrade in vivo. Because Weber teaches for example that "the device of the present invention is biodegradable or hydrolysable in vivo" (e.g. column 3, lines 30-31), one of skill in the art would not be motivated to combine these biodegradable elements with elements from a disclosure that teaches devices constructed from non biodegrade elements (e.g. Ullman) because to do so would compromise the operability of Weber's biodegradable sensors by preventing them from degrading into materials capable of passing through human kidney membrane. Consequently, the Weber disclosure teaches away from the Ullman disclosure ("If when combined, the references 'would produce a seemingly inoperative device,' then they teach away from their combination." *In re Gurley*, 27 F.3d 551, 553, 31 U.S.P.Q.2d 1130 (Fed. Cir. 1994)). In this context, M.P.E.P. § 2143.03 notes that if a proposed modification would render the prior art invention unsatisfactory for its intended purpose (e.g. being biodegradable or hydrolysable in vivo), then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984). For this additional reason, Applicants respectfully request a withdrawal of the rejection under 35 U.S.C. §103(a).

In addition, the various elements of Applicant's claimed invention together provide operational advantages over Weber and Ullman. In addition, Applicant's invention solves problems not recognized by Weber and Ullman. Thus, Applicants submit that independent claims 1 and 38 are allowable over Weber and Ullman. Further, the dependent claims are submitted to be allowable over Weber and Ullman in the same manner, because they are dependent on the independent claims, and thus contain all the limitations of the independent claims. In addition, the dependent claims recite additional novel constellations of elements not shown by Weber and Ullman.

IV. Conclusion

In view of the above, it is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that

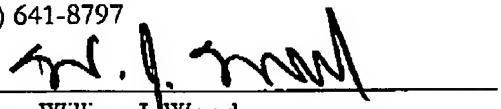
can be resolved in a telephone interview, the Examiner is urged to call Applicant's undersigned attorney.

Respectfully submitted,

GATES & COOPER LLP
Attorneys for Applicant(s)

Howard Hughes Center
6701 Center Drive West, Suite 1050
Los Angeles, California 90045
(310) 641-8797

Date: June 13, 2008

By: 
Name: William J. Wood
Reg. No.: 42,236

WJW/sjm

G&C 130.62-US-01